

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)



Applicant's or agent's file reference PJS/P5758WO		FOR FURTHER ACTION		See Notification of Transmittal of International Preliminary Examination Report (PCT/IPEA/416)
International application No. PCT/EP97/02369	International filing date (day/month/year) 09/05/1997	Priority date (day/month/year) 10/05/1996		
International Patent Classification (IPC) or national classification and IPC A61B6/00				
Applicant OSTEOMETER MEDITECH A/S et al.				



1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 7 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☒ Certain defects in the international application
- VIII ☒ Certain observations on the international application

Date of submission of the demand 03/12/1997	Date of completion of this report 1. 07. 98
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International application No. PCT/EP97/02369

I. Basis of the report

1. This report has been drawn on the basis of (*substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.*):

Description, pages:

1-9 as originally filed

Claims, No.:

1-9 as originally filed

Drawings, sheets:

1/5-5/5 as originally filed

2. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

4. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application.
- ☒ claims Nos. 2, 4-9.

because:

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☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):

☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 2, 4-9 are so unclear that no meaningful opinion could be formed (*specify*):

see separate sheet

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for the said claims Nos. .

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1, 3
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1, 3
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1, 3
	No:	Claims	

2. Citations and explanations

see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

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VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

III:

- III.1 The subject-matter of dependent **claim 2** does not impose any further clear **structural restrictions** to the **apparatus** as claimed in **Claim 1**. Therefore, it has not been possible to take **claim 2** into account for comparison to any known prior art **apparatus**.
- III.2 The subject-matter of **Claim 4** relates to a **method** of **using** the claimed densitometry apparatus rather than clearly defining the **apparatus** in terms of its **technical features**. The intended limitations are therefore not clear from this claim, contrary to the requirements of **Article 6 PCT**, and it has not been possible to carry out a substantial examination of said claim and **claims 5 to 8** depending therefrom.

V:

- V.1 **Technical Field:** **apparatus** for **measuring bone information**
- V.2 **Closest State of the Art:** Document **D1=:** **EP-A-0411155** discloses an **apparatus for measuring bone shape and a system for evaluating bone** that comprises means for acquiring and first storing means for storing information relating to bone density within a body area, second storing means, means for defining a body area in relation to which to select or from which to acquire bone information for processing.
- V.3 **Disadvantage:** Since the system is entirely automated it does not allow for taking account of any particularities that are typical for an individual patient or for a particular bone disorder.
- V.4 **Problem to be Solved:** provision of a bone densitometry apparatus that allows for repeating particular measurements reliably on the same patient at different times and to make the measurement on many different patients in a consistent way
- V.5 **Novelty** of the **independent claims** [Article 33(2) PCT]: The body area defining means is **responsive** to an **operator's choice** of information stored in the **second memory**, wherein said information stored in the second memory relates to a **plurality of bone disorder treatment regimes**.

V.6 **Inventive Activity** [Article 33(3) PCT]: Though document **D1** suggests to use records of medication for therapy for use in combination with the bone information data, the skilled person would not deduce from this suggestion to store said medication data in the second memory in order to design a hardware structure that drives the body area defining means is **response** to an **operator's choice** among the **plurality of bone disorder treatment regimes** stored in the **second memory**. The other known prior art documents are still farther away from the subject-matter of **claim 1**.

Claim 3 is directed to a further embodiments of the invention.

VII:

- VII.1 The independent claim, **Claim 1**, neither has been drafted in the two-part form in accordance with **Rule 6.3(b) PCT**, with those features known in combination from the prior art (document **D1**) being placed in a preamble [**Rule 6.3(b)(i) PCT**] and with the remaining features being included in a characterising part [**Rule 6.3(b)(ii) PCT**], nor did the applicant provide any convincing reasons against the two-part form of claim [see the **PCT Guidelines PCT/GL/3 III, 2.3a**].
- VII.2 The features of the claims should have been provided with reference signs placed in parentheses [**Rule 6.2(b) PCT**].
- VII.3 In order to meet the requirements of **Rule 5.1(a)(ii) PCT**, document **D1** should have been identified in the description, the relevant background art disclosed therein being briefly discussed.

VIII:

- VIII.1 Although **Claims 1** and **4** have been drafted as separate independent claims, they appear to relate effectively to the same subject-matter (**apparatus for bone densitometry**) and to differ from each other only with regard to the definition of the subject-matter for which protection is sought and in respect of the terminology used for the features of that subject-matter. The aforementioned claims therefore **lack conciseness**. Moreover, **lack of clarity** of the claims as a whole arises, since the plurality of independent claims makes it difficult, if not impossible, to determine the matter for which protection is sought, and places an undue burden on others seeking to establish the extent of the protection.

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- VIII.2 Hence, **Claims 1** and **4** do not meet the requirements of **Article 6 PCT**.
At least some of the features of the subject-matter of **claim 3** relate to the **performance** of the claimed **apparatus** or to the **method** how the claimed apparatus is **used** to solve the problem posed rather than imposing clear **structural** characteristics to it which leads to a lack of clarity concerning the category of the claim, in contradiction to **Article 6 PCT**.